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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SUGHRUE MION ZINN MACPEAK & SEAS  
2100 PENNSYLVANIA AVENUE N W  
WASHINGTON DC 20037

EXAMINER

BERMAN, A

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Applicant(s)

09/125,814

Applicant(s)

DOHI ET AL.

Examiner

Alysia Berman

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-32, 34 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-32, 34 and 36-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Receipt is acknowledged of the Notice of Appeal filed November 7, 2000 and the request for a CPA, amendment and Declaration filed March 14, 2001. Claims 46-50 have been added. Claims 19-32, 34 and 36-50 are pending.

#### ***Continued Prosecution Application***

2. The request filed on March 14, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/125814 is acceptable and a CPA has been established. An action on the CPA follows.

#### ***Response to Amendment***

3. The amendment filed March 14, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: the drug is unevenly dispersed on or in the water-absorbing and water-insoluble base material in claim 48.

Applicant is required to cancel the new matter in the reply to this Office Action.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 48-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 48 recites that the drug is unevenly dispersed on or in the water-absorbing and water-insoluble base material. The disclosure is directed to a composition wherein the drug is unevenly dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. This is not equivalent to uneven dispersion on or in one base material alone. Applicants have not pointed out support for such an amendment.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

7. Claims 32, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Regarding claim 32, the phrase "insulin-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

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9. Claims 46 and 47 are indefinite because claim 46 appears to recite a Markush group but is not written in proper Markush form. The proper language for a Markush group is, for example, "selected from the group consisting of A, B and C" or "wherein A is B or C." Correction is requested.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 19-26, 28-32, 34 and 36-50 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,613,500 (Suzuki et al. '500).

US '500 discloses a powdery composition comprising a polypeptide (col. 2, line 57 to col. 3, line 25) that is absorbed onto or into a water-absorbing and water-insoluble base (col. 4, lines 21-41 and col. 5, lines 53-65). For crystalline cellulose and other water-absorbing and water-insoluble base materials, see column 4, lines 21 to 24. This composition may be combined with a water-absorbing and water-soluble (gel-forming) base material (col. 5, lines 10-25). For hydroxypropyl cellulose and other water-absorbing and gel-forming base materials, see column 5, lines 10-17. The amount of water-absorbing and gel-forming base material is from 0.1-60 wt.% based on the amount of water-absorbing and water-insoluble base material (col. 5, lines 22-25).

US '500 discloses at column 5, lines 53 to 65 that the drug is adhered to or dispersed in the water-absorbing and water-insoluble base material. Therefore, even with the addition of a water-absorbing and gel-forming base material, it is reasonable to expect that the drug would be dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. US '500 discloses at column 5, line 65 to column 6, line 53 that the composition may be made by either mechanically mixing the base materials and the drug, dispersing the drug and the base materials in a solvent and freeze-drying the mixtures. The particle size of more than 90% of the resultant particles is 10-250 microns (col. 5, lines 26-28 and col. 6, lines 6-9).

Claims 20-25 and 38-41 are product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, claims 20-25 do not require that the product be made by the recited processes.

It is the Examiner's primary opinion that US '500 anticipates the instantly claimed composition. However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time of the invention to mix the drug with the water-absorbing and water-insoluble base material before mixing with the water-absorbing and gel-forming

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base material as disclosed in US '500 thereby obtaining uneven distribution of the drug on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. The motivation to do so is the desire of obtaining efficient absorption of the drug by nasal administration (abstract).

### ***Response to Arguments***

12. Applicant's arguments filed 05 May 2000 have been fully considered but they are not persuasive.

13. Applicant argues that US '500 does not disclose, teach or suggest the instant invention. The Declaration filed March 14, 2001 has been considered but is not commensurate in scope with the instant independent claims. The Declaration is limited to a process of making the composition by either mixing microcrystalline cellulose with the drug prior to mixing with hydroxypropyl cellulose, using a small particle size of hydroxypropyl cellulose or dispersing microcrystalline cellulose with the drug, freeze-drying the mixture and then mixing with hydroxypropyl cellulose. In any event, US '500 clearly discloses that the drug is distributed either on or in the water-absorbing and water-insoluble base material (microcrystalline cellulose) and does not make any mention of the drug being distributed on or in the water-absorbing and gel-forming base material. The claims as written do not require any limitations that would distinguish the instant composition from that of the prior art.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,613,500 in combination with US 5,262,871 (Makino et al. '871).

US '500 discloses all of the limitations of the claims as stated above. US '500 does not teach the use of non-peptide/non-proteinaceous drug. US '871 discloses non-peptide/non-proteinaceous drugs (col. 7, line 60 to col. 8, line 26) for use in powdery nasal compositions (col. 4, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a non-peptide/non-proteinaceous drug as taught in US '871 for a



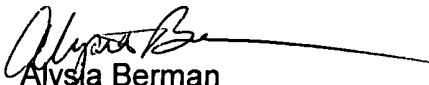
peptide-proteinaceous drug in the composition of US '500 with the reasonable expectation of obtaining efficient absorption of the drug through nasal administration.


**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

  
Alysia Berman  
Patent Examiner  
May 16, 2001

  
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